

## REMARKS

Claims 51-88 are pending. Claims 51-54, 58-68 and 72-77 are under examination. Claims 51-88 have been canceled. New claims 89-109 have been added. Support for the new claims can be found throughout the specification and the claims as filed. In particular, support for new claims 89-98 can be found on page 6, lines 1-20; page 7, line 7, through page 9, line 5; page 16, line 18, through page 17, line 23; page 40, line 1, through page 42, line 3; and in the original claims. Support for new claims 99-107 can be found, for example, on page 4, line 20, through page 5, line 20; page 7, line 7, through page 9, line 5; page 16, line 18, through page 17, line 23; page 40, line 1, through page 42, line 3; and in the original claims. Additional support for new claims 95 and 106 can be found, for example, on page 9, lines 26-30, and page 10, lines 29-32. Accordingly, these new claims do not raise an issue of new matter and entry thereof is respectfully requested.

Without addressing the merits of the rejections set forth in the Office Action mailed November 2, 2005, Applicants have canceled claims 51-88 without prejudice to Applicants pursuing these claims in a related application.

For the Examiner's convenience, set forth below is a table of concordance between the previously pending claims and new claims 89-109.

<b>Current Claims</b>	<b>Previous Claims</b>
89-92	51-54
93-103	58-68
104-109	72-77

Regarding the Priority Claim

In the Office Action, it has been requested that the first line of the specification be updated to reflect the priority claim. The first page of the specification has been amended to reflect the priority claim as requested by the Examiner. Accordingly, Applicant respectfully requests that this objection be withdrawn.

Rejection Under 35 U.S.C. § 112, First Paragraph

The rejection of claims 51-54, 58-68 and 72-77 under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement is respectfully traversed. Applicant respectfully submits that this rejection has been rendered moot by the cancellation of these claims. Accordingly, Applicant respectfully requests that this rejection be withdrawn.

With respect to new claims 89-109, Applicant points out that the claims are directed to determining the risk for tumor recurrence or spread or prognosis of survival in a patient suffering from prostate cancer by determining BAG-1 gene expression. Applicant further points out that the Office Action acknowledges on pages 3- 4 the enablement of methods for determining the risk of tumor recurrence or spread in a patient suffering from prostate cancer and a method for determining prognosis in a patient suffering from prostate cancer by determining BAG-1 gene expression. Applicant respectfully submits that the specification provides sufficient description and guidance to enable new claims 89-109.

Rejection Under 35 U.S.C. § 103

The rejection of claims 51-54, 58-68 and 72-77 under 35 U.S.C. § 103 as allegedly obvious over Froesch et al., Proc. Am. Assoc. Cancer Res. Meeting March 1998 89:13, in view of Zapata et al., Breast Cancer Res. Treatment 47:179-140 (1998), and Sano et al., U.S. Patent No. 5,665,539 is respectfully traversed. Applicant respectfully submits that this rejection has been rendered moot by the cancellation of these claims. Accordingly, Applicant respectfully requests that this rejection be withdrawn.

With respect to new claims 89-109, Applicant respectfully submits that these claims are unobvious over Froesch et al., alone or in combination with Zapata et al. and/or Sano et al. New

independent claim 89 is directed to a method for determining the risk of tumor recurrence or spread in a patient suffering from prostate cancer by determining a BAG-1 gene expression level in a cancerous prostate tissue sample from the patient; and comparing the BAG-1 gene expression level in the patient to a reference BAG-1 gene expression level, the reference BAG-1 gene expression level being a level of BAG-1 gene expression above which correlates with an increased risk of tumor recurrence or spread and below which correlates with a decreased risk of tumor recurrence or spread, thereby determining the risk of tumor recurrence or spread in the patient. New independent claim 99 is directed to a method for determining a prognosis of survival in a patient suffering from prostate cancer by determining a BAG-1 gene expression level in a cancerous prostate tissue sample from the patient; and comparing the BAG-1 gene expression level in the patient to a reference BAG-1 gene expression level, the reference BAG-1 gene expression level being a level of BAG-1 gene expression above which correlates with decreased survival and below which correlates with increased survival, thereby determining a prognosis of survival in the patient.

In contrast to the claimed methods, Froesch et al. does not teach or suggest methods for determining the risk of tumor recurrence or spread or for determining prognosis of survival in a patient suffering from prostate cancer by determining BAG-1 gene expression. At best, Froesch et al. describes the observation that BAG-1L is expressed in prostate cancers and enhances androgen receptor function. However, Froesch et al. provides no teaching or suggestion that the level of BAG-1 gene expression can be used to determine the risk of tumor recurrence or spread or for determining prognosis of survival in a patient suffering from prostate cancer by determining BAG-1 gene expression. Absent such a teaching or suggestion, Applicant respectfully submits that Froesch et al. cannot render the claimed methods obvious.

Furthermore, neither of Zapata et al. nor Sano et al. cure the deficiencies of Froesch et al. Zapata et al. describes the expression of multiple apoptosis-regulatory genes in human breast cancer cell lines and primary tumors. Sano et al. describes immuno-PCR for detecting antigens. One skilled in the art would have had no motivation to combine the description in Froesch et al. of the expression of BAG-L1 in prostate cancers with the description in Zapata et al. of the expression of apoptosis-regulatory genes in breast cancer and/or Sano et al. for immuno-PCR to achieve the claimed methods for determining the risk of tumor recurrence or spread or for

determining prognosis of survival in a patient suffering from prostate cancer by determining BAG-1 gene expression. Even if, *arguendo*, one were to combine these references, there still would have been no teaching or suggestion that BAG-1 expression could be used to determine the risk of tumor recurrence or spread or to determine prognosis of survival in a patient suffering from prostate cancer by determining BAG-1 gene expression, absent the teaching in the specification. Accordingly, Applicant respectfully submits that a *prima facie* case of obviousness has not been established. Applicant respectfully submits that new claims 89-109 are unobvious over Froesch et al., alone or in combination with Zapata et al. and/or Sano et al.

In light of the amendments and remarks herein, Applicant submits that the claims are now in condition for allowance and respectfully requests a notice to this effect. The Examiner is invited to call the undersigned agent if there are any questions.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502624 and please credit any excess fees to such deposit account.

Respectfully submitted,

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